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AMENDMENTS TO THE SPECIFICATION

Please amend paragraphs [0022], [0036], and [0040] as indicated below; deletions are indicated with ~~striketthrough~~ and insertions are indicated as underlined. Please insert paragraphs [0040A] – [0040Z] after paragraph [0040].

[0022] FIGS. 1 and 2 depict one embodiment of a prosthetic knee suitable for use in preferred embodiments. FIGS. 1 and 2 correspond to FIGS. 4 and 5, respectively, of U.S. patent Publication 2001/0029400A1 (application Ser. No. 09/767,367), filed Jan. 22, 2001, entitled "ELECTRONICALLY CONTROLLED PROSTHETIC KNEE," the entire disclosure of which is hereby incorporated by reference herein. More specifically, the description of the drawings and the item numbers depicted in the drawings are described in detail in the above referenced patent publication. FIG. 1 is a detailed exploded perspective view of a magnetorheologically actuated prosthetic knee having features and advantages in accordance with one preferred embodiment of the present invention. FIG. 2 is a cross section view of the prosthetic knee of FIG. 1.

[0036] Other ingredients can be optionally added to the carrier fluids of preferred embodiments to enhance the performance properties of preferred carrier fluids. In some embodiments, preferred additives include, but are not limited to, functionalized carrier fluids. In embodiments comprising perfluorinated polyethers, desirable additives can also include, but are not limited to, functionalized PFPE oils as well as derivatized fluoropolymers. Suitable candidates for monofunctionalized PFPE derivatives include, but are not limited to silane, phosphate, hydroxyl, carboxylic acid, alcohol and amine functions. Suitable candidates for difunctional PFPE derivatives include, but are not limited to, dihydroxyldihydroxyl, ethoxy ether, isocyanate, aromatic, ester and alcohol functions. In some embodiments, functionalized perfluorinated polyether fluid additive comprises one or more functional groups selected from the group consisting of silane, phosphate, hydroxyl, carboxylic acid, amine, dihydroxyl, ethoxy ether, isocyanate, aromatic, ester and alcohol functions. More specifically, in one embodiment comprising perfluorinated polyethers, a preferred functionalized PFPE oil comprises a poly(hexafluoropropylene epoxide) with a carboxylic acid located on the terminal fluoromethylene group. As presently contemplated preferred functionalized PFPE oils are Krytox(157 FSL and Krytox.RTM. 157 FSM available from E.I. du Pont de Nemours

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and Company, (Wilmington, Del., USA). In another embodiment, a preferred fluoropolymer comprises a parafluoropropene and oxygen polymerized amide derivative. As presently contemplated a preferred parafluoropropene and oxygen polymerized amide derivative additive is FOMBLIN DA 306 available from Solvay Solexis (Thorofare, N.J., USA).

[0040] When the MR fluids as described herein are used in combination with a prosthetic knee, for example, a knee as described in U.S. patent Publication No. 2001/0029400A1, certain characteristics of the fluid as well as the knee may be desired. In one embodiment, such as shown in FIGS. 4 and 5 of U.S. 2001/0029400A1 and FIGS. 1 and 2 disclosed herein and described in further detail below, a knee may contain a cavity or passage for holding MR fluid between a plurality of rotors and stators. The number of rotors and stators in certain embodiments may be increased or reduced in order to alter the off-state or low-end torque properties of the MR fluid used in combination with the knee. In one embodiment, the number of rotors and stators preferably range from about 50 to about 90, preferably from about 55 to about 70, but also including about 57, 59, 61, 63, 65, 67, and ranges encompassing these amounts. The knee cavity may contain a volume of about 1 to about 10 ml, preferably from about 2 to about 9 ml, more preferably from about 3 to about 8 ml, but also including about 4, 5, 6, and 7 ml. In one embodiment, the MR fluid fills the cavity to about 70% of its total volume, but may range from about 50 to about 100% as well about 55, 60, 65, 75, 80, 85, 90 and 90%. The MR fluid advantageously demonstrates one or more of the following: relatively low volatility, stable viscosity, thermal stability, and a stable composition. In addition, in certain embodiments it is desirable that the cavity or passage containing the MR fluid does not exhibit undesirable pressure levels. Without wishing to be bound by any theory, it is believed that an unsuitable fluid may release gases or volatilize causing pressure within the prosthetic knee to increase to an undesirable level. If the pressure is too high, the integrity of the prosthetic knee seals can be compromised. In certain embodiments it is desirable that a prosthetic knee utilizing a MR fluid produces torque of about 0.1 to about 200 Newton-meters, more preferably about 0.3 to about 150 Newton-meters, even more preferably about 0.5 to about 100 Newton-meters, but also including about 0.8, 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 20, 30, 40, 50, and 75 Newton-meters.

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[0040A] FIGS. 1 and 2 show a controllable rotary prosthetic knee joint 210 having features and advantages in accordance with one preferred embodiment of the present invention. The prosthetic knee 210 generates controllable dissipative forces preferably substantially along or about the knee axis of rotation 224.

[0040B] The electronically controlled knee 210 generally comprises a generally central core 212 in mechanical communication with a pair of rotatable side plates 216, 218, an electromagnet 214, a plurality of blades or rotors 220 in mechanical communication with a rotatable inner spline 222, a plurality of blades or stators 230 in mechanical communication with a rotatable outer spline 232, a pair of ball bearings 226, 228 for transferring rotary motion to a pair of outer side walls or forks 236, 238. The rotation is substantially about the knee axis of rotation 224.

[0040C] The plurality of rotors 220 and stators 230 are preferably interspersed in an alternating fashion and the gaps or microgaps between adjacent blades 220 and 230 comprise thin lubricating films of a magnetorheological (MR) fluid, which thereby resides in the cavity or passage formed between the inner spline 222 and the outer spline 232. This preferred embodiment provides a controllable and reliable artificial knee joint, which advantageously has a wide dynamic torque range, by shearing the MR fluid in the multiple gaps or flux interfaces between adjacent rotors 220 and stators 230.

[0040D] Preferably, end-threaded rods 248 and nuts 250 are used to secure selected components of the prosthetic knee 210, thereby allowing a straightforward assembly and disassembly procedure with a minimum of fasteners. Alternatively, or in addition, various other types of fasteners, for example, screws, pins, locks, clamps and the like, may be efficaciously utilized, as required or desired, giving due consideration to the goals of providing secure attachment, and/or of achieving one or more of the benefits and advantages as taught or suggested herein.

[0040E] Preferably, the core 212 and associated side plates 216, 218 are formed of a magnetically soft material of high flux saturation density and high magnetic permeability. Thus, when the electromagnet 214 is actuated a magnetic field, circuit or path is generated or created within the knee joint 210. In one preferred embodiment, the magnetic field passes longitudinally (parallel to the axis of rotation 224) through the central core 212, radially through the side plate 218, laterally (parallel to lateral direction 242) through the interspersed set of rotors 220 and stators 230

and the magnetorheological (MR) fluid, and radially through the side plate 216. The orientation or positioning of the electromagnet 214 and the direction of current flow through it determines the polarity of the magnetic field, and thereby determines whether the magnetic field passes radially inwards or outwards through the side plate 218, and hence in the correspondingly opposite direction through the side plate 216. The portion of the magnetic field passing through the core 212 and side plates 216, 218 generally defines the magnetic return path while the active or functional magnetic field is generally defined by the magnetic path through the rotors 220, stators 230 and MR fluid residing therebetween.

[0040F] The core side plate 216 preferably comprises a circular groove 260 to receive an O-ring 262 (FIG. 1), lip seal or gasket and the like. This provides a dynamic seal between the rotatable side plate 216 and the inner surface of the rotatable outer spline 232 and prevents leakage of MR fluid from the knee 210. The other side plate 218 is similarly configured to receive an O-ring 262 (FIG. 1) and provide a dynamic seal. In an alternative preferred embodiment, two grooves or flanges are provided on the inner surface of the outer spline 232 to receive O-rings or the like and provide a dynamic seal between the core side plates 216, 218 and the outer spline 232.

[0040G] The O-rings 262 are fabricated from a suitable rubber material or the like such as Viton, Teflon and Neoprene among others. In one preferred embodiment, the O-rings 262 have an inner diameter of about 50 mm and a width of about 1.5 mm. In other preferred embodiments, the dynamic seals can be dimensioned and/or configured in alternate manners with efficacy, as required or desired, giving due consideration to the goals of providing reliable seals, and/or of achieving one or more of the benefits and advantages as taught or suggested herein.

[0040H] The inner surface of the core side plate 216 preferably has a generally circular shoulder or step 264 for aligning or locating with the inner spline 222 (FIG. 1). The outer surface of the core plate 216 preferably has a generally ring-shaped shoulder or step 266 for aligning or locating with the outer fork 236 (FIG. 1). Optionally, the step 266 may include a cut 268 to allow clearance space for electrical wires or leads. Other holes around the central cavity 256 may be provided for passage of electrical wires or leads. Preferably, the outer surface of the core side plate 216 includes a tapered portion 270. This advantageously decreases weight, saves material and also provides clearance space to facilitate assembly.

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[0040I] The core side plate 216 is preferably fabricated from a material having a high saturation flux density, a high magnetic permeability and low coercivity. Advantageously, this facilitates in the construction of an artificial knee or brake that is compact and light weight, and also strong. In one preferred embodiment, the core plate 216 comprises an integral unit. In another preferred embodiment, the core plate 216 is formed of laminated sheets to advantageously reduce or minimize eddy losses.

[0040J] Preferably, the core plate 216 comprises an iron-cobalt (FeCo) high magnetic saturation alloy. In one preferred embodiment, the core plate 216 comprises Vacoflux 50 as available from Vacuumschmelze of Hanau, Germany. In another preferred embodiment, the core plate 216 comprises Iron-Cobalt High Saturation Alloy (ASTM A-801 Type 1 Alloy). In yet another preferred embodiment, the core plate 216 comprises Vacoflux 17 as available from Vacuumschmelze of Hanau, Germany. In a further preferred embodiment, the core plate 216 comprises Hiperco Alloy 50. In other preferred embodiments, the core plate 216 can be efficaciously fabricated from alternate soft magnetic materials or the like, as required or desired, giving due consideration to the goals of providing a suitably compact, light weight and/or durable prosthetic knee joint, and/or of achieving one or more of the benefits and advantages as taught or suggested herein.

[0040K] In one preferred embodiment, the material comprising the core plate 216 has a saturation flux density of about 2.2 Tesla. Such a high saturation flux density is desirable because it allows a compact and light weight design. For example, if a material having a lower saturation flux density was utilized, the cross-sectional area of the return path through the core plate 216 in the direction of the applied magnetic field would have to be increased to achieve the same dynamic torque range. In other preferred embodiments, the core side plate saturation flux density can be higher or lower, as needed or desired, giving due consideration to the goals of providing a suitably compact, light weight and/or durable prosthetic knee joint, and/or of achieving one or more of the benefits and advantages as taught or suggested herein.

[0040L] Preferably, the core side plate 216 is formed by machining followed by heat treatment in a hydrogen atmosphere to achieve optimal magnetic properties. In other preferred embodiments, the core side plate 216 can be efficaciously fabricated from other techniques, for example, casting, forging, molding, laminating, among others, as required or desired, giving due

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consideration to the goals of providing desired magnetic properties and a suitably compact, light weight and/or durable artificial knee, and/or of achieving one or more of the benefits and advantages as taught or suggested herein.

[0040M] The inner spline 222 is preferably generally cylindrical in shape and comprises a substantially central cylindrical cavity or through hole 276 for receiving the electromagnet or magnetic coil 214 (FIG. 1). Alternatively, other suitable shapes for the inner spline 222 and cavity 276 may be efficaciously utilized, as needed or desired.

[0040N] Preferably, the inner spline 222 comprises a plurality of approximately equally spaced longitudinal through holes 278 arranged in a generally circular fashion to receive end-threaded rods or bolts and the like to secure selected components of the prosthetic knee 210, such as the core side plates 216, 218 and the inner spline 222. These holes 278 are generally aligned with corresponding holes 258 of the core side plates 216, 218.

[0040O] In one preferred embodiment, the inner spline 222 comprises five holes 278. In another preferred embodiment, the inner spline 222 comprises three holes 278. Alternatively, fewer or more holes 278 arranged in other fashions may be provided, as needed or desired.

[0040P] The inner spline 222 preferably comprises a circular groove 260 at each end to receive respective O-rings 282 (FIG. 1) or gaskets and the like. This provides a static seal between the inner spline 222 and the side plates 216, 218, since these components rotate together during knee rotation, and prevents leakage of MR fluid from the knee 210. In an alternative preferred embodiment, a respective groove or flange is provided on the inner surfaces of either or both plates 216, 218 to receive O-rings or the like and provide a static seal.

[0040Q] The O-rings 282 are fabricated from a suitable rubber material or the like such as Viton, Teflon and Neoprene among others. In one preferred embodiment, the O-rings 282 have an inner diameter of about 30.5 mm (1.201 inches) and a width of about 0.76 mm (0.030 inches). In other preferred embodiments, the static seals can be dimensioned and/or configured in alternate manners with efficacy, as required or desired, giving due consideration to the goals of providing reliable seals, and/or of achieving one or more of the benefits and advantages as taught or suggested herein.

[0040R] The outer surface of the inner spline 222 preferably has a plurality of approximately equally spaced longitudinal grooves 284 which are adapted to engage corresponding teeth of the

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rotors 220. In one preferred embodiment, the grooves 284 are generally semi-circular in shape. In another preferred embodiment, the grooves 284 are generally rectangular or square shaped with rounded corners. In other preferred embodiments, the grooves 284 can be efficaciously shaped and/or configured in alternate manners, as required or desired, giving due consideration to the goals of providing reliable load transmission from the rotors 220 to the inner spline 222, and/or of achieving one or more of the benefits and advantages as taught or suggested herein.

[0040S] The inner spline 222 is preferably fabricated from titanium or a titanium alloy, and more preferably from 16A1-14V titanium alloy. Advantageously, the use of titanium or titanium alloys provides a near zero magnetic permeability and a yet strong, hard surface with low weight to engage the rotors and transmit torque from them. An additional benefit is that the high resistivity of the material (titanium or titanium alloy) reduces energy losses due to induced eddy currents. In other preferred embodiments, the inner spline 222 can be efficaciously fabricated from other metals, alloys, plastics, ceramics among others, as required or desired, giving due consideration to the goals of providing an inner spline 222 of near zero magnetic permeability, and a suitably compact, light weight and/or durable artificial knee, and/or of achieving one or more of the benefits and advantages as taught or suggested herein.

[0040T] Preferably, the inner spline 222 is formed by machining. In other preferred embodiments, the inner spline 222 can be efficaciously fabricated from other techniques, for example, casting, forging, molding, among others, as required or desired, giving due consideration to the goals of providing a suitably compact, light weight and/or durable artificial knee, and/or of achieving one or more of the benefits and advantages as taught or suggested herein.

[0040U] In one preferred embodiment, the prosthetic knee 210 comprises an angle sensing potentiometer 322 (FIG. 1). The potentiometer 322 is connected to an arm 324 and a mounting plate 326. The mounting plate 326 is connected to the fork 238 utilizing screws 328 or the like and spacers 330. An end 332 of the arm 324 is mechanically connected to the angled outer surface 334 of the fork 238 utilizing suitable screws or the like.

[0040V] In one preferred embodiment of the present invention, the prosthetic knee 210 further comprises an extension assist to help straighten the leg by urging or biasing the leg to extension by applying a controlled torque or force. Any one of a number of devices, such as a

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spring-loaded extension assist, as known in the art may be used in conjunction with the present invention.

[0040W] The mounting forks 236, 238 (FIG. 1) of the magnetorheologically actuated prosthetic knee 210 are preferably in mechanical communication with the bearings 226, 228 respectively and transfer rotary motion to a pylon or artificial shin portion of the amputee. Threaded studs 306 or other suitable connectors or fasteners are used to facilitate connection of the mounting forks 236, 238 to a pylon or artificial shin portion of the amputee.

[0040X] Preferably, the mounting forks 236, 238 are fabricated from anodized 7075-T6 aluminum alloy. In other preferred embodiments, the mounting forks 226, 238 can be efficaciously fabricated from other metals, alloys, plastics, ceramics among others, as required or desired, giving due consideration to the goals of providing suitably strong, durable, light weight and/or substantially non-magnetic mounting forks 226, 238, and/or of achieving one or more of the benefits and advantages as taught or suggested herein.

[0040Y] In one preferred embodiment, the mounting forks 236, 238 are formed by machining. In other preferred embodiments, the mounting forks 236, 238 can be efficaciously fabricated from other techniques, for example, casting, forging, molding, among others, as required or desired, giving due consideration to the goals of providing a suitably compact, light weight and/or durable artificial knee, and/or of achieving one or more of the benefits and advantages as taught or suggested herein.

[0040Z] In one preferred embodiment, and as shown in FIG. 1, the prosthetic knee 210 further comprises a flexion stop system or assembly comprising a cushioned stop or restraint assembly or system 246. The flexion stop system controls the maximum allowable flexion angle by physically limiting the rotation between the outer side forks 236, 238 and the outer spline 232, and hence the rotation of the knee joint. The stop system 246 (FIG. 1) generally comprises a plurality of stops, bands or strips 312, 314 and 316.